IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE SUZANNE PARISIAN, M.D.

INTRODUCTION

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") move to exclude the testimony of Plaintiff's expert, Suzanne Parisian, M.D., in its entirety for the cases identified in Exhibit A.[1]

Dr. Suzanne Parisian is a non-practicing pathologist who has not treated a patient in nearly 30 years. Wearing the mantle of "regulatory expert," she is a well-traveled advocate for the plaintiffs' bar: it seems she has been retained to testify on every imaginable drug or medical device known to the court system.

Although this Court has not yet ruled upon whether (or to what extent) her testimony is admissible in the pelvic mesh MDL proceedings, Dr. Parisian is the subject of countless

[1] Plaintiffs' designation states that they recognize the Fourth Circuit's affirmance of this Court's exclusion of evidence of compliance with the 510(k) process and "reserve the right to designate" Dr. Parisian "[i]n the event of a contrary ruling." Exh. B: Pls. General Expert Desig., p. 2. Ethicon understands this to mean that Dr. Parisian is not designated at all if no FDA evidence is admitted, even though this is potentially inconsistent with Dr. Parisian's current disclaimer of reliance on FDA regulations. In addition, Ethicon notes that this "reservation of right to designate" in some instances puts Plaintiffs' number of experts over the allotted five.

decisions from federal courts across the country. To be fair, some courts have permitted her to testify, and some have permitted her to testify on limited topics. Yet oft-quoted courts have described her opinions as "astonishing," "egregious,"[2] and "woefully deficient,"[3] and have accordingly excluded her testimony. *In re Trasylol* articulated the concerns with Dr. Parisian as follows:

> Plainly stated, Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding the opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon inference in order to offer her "takeaway" or "take home message" with respect to intent, knowledge, or causation in a manner unrelated to any regulatory expertise. Her testimony is unreliable and would not be of assistance to the jury**.**

In re Trasylol Prods. Liab. Litig., 709 F.Supp.2d 1323, 1351 (S.D. Fla. 2010) (excluding entire testimony after *Daubert* hearing).

In the instant case, Dr. Parisian has prepared reports on two products: the Prolift +M and TVT-Secur (a/k/a TVT-S). Each report weighs in at approximately 100 pages and—as other courts have described her reports—contains a labyrinth of opinions. Given the nature and

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[2] *In re Trasylol*, 709 F. Supp. 2d at 1342-1343 (S.D. Fla. 2010) (commenting after *Daubert* hearing at which Parisian testified: "An instance I found particularly egregious was Dr. Parisian's apparent effort to construct a factual scenario, entirely divorced from any regulatory expertise, to support the Plaintiffs' theory as to Bayer's knowledge…Dr. Parisian's willingness to offer 'expert' opinion on such flimsy evidence and withhold any disclosures in advance is simply astonishing.").

In the *Prempro* MDL, the United States Court of Appeals for the Eighth Circuit affirmed the District Court's post-trial decision to strike Dr. Parisian's entire trial testimony because she refused to abide by the court's rulings that limited her testimony. *See In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009). In a lengthy opinion devoted to her tactics, the *Prempro* MDL court cautioned: "Dr. Parisian's punitive damages stage testimony reveals 'how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis.'" *In re Prempro Products Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008).

[3] *In re Human Tissue Products Liab. Litig.*, 582 F. Supp.2d 644, 666 (D. N.J. 2008) (scientific conclusions "woefully deficient" and "nothing more than pure speculation").

format of Dr. Parisian's prepared reports, it is immediately apparent that many of her stated opinions are inadmissible. Her testimony should be excluded in its entirety for the following reasons:

First, although Dr. Parisian claims to be a "regulatory expert," her reports and deposition testimony confirm that she fully expects to provide the jury with her opinions on highly scientific topics including product development, design, risks, testing, manufacturing, studies, and the standard of care for treating physicians. She is not qualified to do so and does not employ a reliable methodology for the panoply of opinions she intends to offer.

Second, Dr. Parisian also states that she will not testify on corporate state of mind or intent, but her reports and testimony paint a different picture: they are full of Dr. Parisian's personal beliefs that Ethicon is a bad actor. This should be excluded because Dr. Parisian is not qualified in the first instance and does not have a reliable methodology. This testimony is also irrelevant and not helpful to the trier of fact.

Third, Dr. Parisian's regulatory opinions are inadmissible because they are irrelevant to the extent she frequently cites to Ethicon allegedly misleading the FDA, or withholding information from the FDA—topics which this Court has repeatedly ruled are not relevant. Her regulatory opinions also amount to impermissible "narrative" testimony, as she simply recites at length internal documents with no analysis. Her opinions also constitute impermissible legal conclusions.

Fourth, Dr. Parisian should not be permitted to opine on foreign regulatory matters because she is not qualified; she does not employ a reliable methodology; and this testimony would not be helpful to the jury.

Fifth, Dr. Parisian's warnings opinions on the Prolift +M are inadmissible. Her deposition testimony reveals that she is not qualified to opine on warnings and she does not apply a reliable methodology. Dr. Parisian freely admits that she does not know the risks of non-mesh or mesh procedures; and she has not spoken to any pelvic floor surgeon, let alone conducted any pertinent research or study to support her conclusions.

Sixth, Dr. Parisian's testimony about the TVT-Secur's warnings should similarly be excluded because she is not qualified and fails to use a reliable methodology.

Seventh, and finally, Dr. Parisian should not be permitted to testify as to any product other than Prolift +M or TVT-Secur—the only products for which she supplied an expert report.

ARGUMENT

I. Legal Standard

Ethicon incorporates by reference the standard of review for the instant motion to exclude as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014).

II. Law & Analysis

Dr. Parisian lists 13 opinions in her 98-page Prolift +M report and 8 opinions in her 112-page TVT-Secur report. Exh. C: Suzanne Parisian Expert Witness Report, MDL 2327, Jan. 30, 2016: Prolift +M ("PM Rep."); Exh. D: Suzanne Parisian Expert Witness Report, MDL 2327, Jan. 30, 2016: TVT-Secur ("TVT-S Rep."). Because these reports share many aspects, much of the discussion below pertains to "all products," meaning exclusion is appropriate irrespective of the product in question. To the extent there are issues particular to either product, such as warnings, they are specified in the headings and corresponding discussions.

A. <u>All Products</u>: Dr. Parisian is not qualified to offer any scientific opinions on causation, product development, risks, design, testing, manufacturing, studies, or the standard of care for treating physicians.

(1) Although Dr. Parisian claims her focus is regulatory, her report and testimony are replete with opinions on highly scientific issues.

As a threshold issue, it is important to note—and debunk—the topics upon which Dr. Parisian seeks to opine. Her report states that she will not "address medical causation or standard of care in terms of the treating physicians," PM Rep. ¶14, 23; TVT-S Rep. ¶14, 23, and she testified at deposition that she would not offer any general or specific causation opinions. Exh. E: Parisian 3/8/16 Prolift +M Dep. Tr. ("PM Dep.") 46:11-47:6. She also testified that she would not offer any opinion about manufacturing defect issues. *See id.* 48:3-49:6.

Despite these statements, Dr. Parisian's report—and her testimony—reveal that she seeks to delve far into the realm of science.[4] Dr. Parisian may not do so, however, because she is unqualified—and even if she were qualified, she does not employ any valid methodology.

(2) Dr. Parisian is not qualified to offer scientific testimony, and similarly she offers no reliable methodology to arrive at her conclusions.

No matter how Dr. Parisian attempts to couch it—which she tries to do by stating that her opinions are given through a "regulatory" framework (*see, e.g.*, TVT-S Rep. ¶68 ("I view my primary role as a FDA regulatory expert"))—it is apparent that she seeks to opine on highly scientific testimony. These include the following opinions, which run the gamut from "safeguards … for conducting ethical research" to "adequate study design or testing" to "clinical consequences for patients of manufacturing changes" to "manufacturing changes" to "[study of

[4] Several courts have similarly noted—and thus addressed—opinions that Dr. Parisian claims she will not offer, but ultimately tries to. *See, e.g., Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 467 (E.D. N.Y. 2011) ("The Court finds that the Plaintiffs' assertion that Dr. Parisian does not offer such opinions to be disingenuous.").

the] short- and long-term risks, changes in tissue ingrowth, properties or healing, [and] inflammation."[5]

Dr. Parisian does not have sufficient qualifications to present this testimony, nor does she employ any methodology—let alone a reliable one. Although she is a licensed medical doctor and pathologist, she has not treated a patient for nearly 30 years. PM Dep. 57:17-24; 58:4-6. She has never performed surgery to treat pelvic organ prolapse and does not recall if she ever implanted or explanted any medical device; if she had, it was "a long time ago." *Id.* 60:23-61:24.

Dr. Parisian has never participated in any animal or cadaver studies regarding any mesh device, PM Dep. 58:15-20, and has never designed or been involved in any clinical trials, protocols or studies regarding any device involving mesh. *Id.* 58:21-59:1; 59:23-60:3. Dr. Parisian has never designed mesh, has never done any biomechanical testing of mesh, and has never done any lab work regarding mesh. *Id.* 59:2-9. She has never tested a polypropylene or mesh explant, nor has she ever inspected or even looked at a mesh explant of any kind under a microscope. *E.g.*, *id.* 59:10-22, 60:4-12 (no testing of any type on the mesh in Prolift +M).[6]

The first time Dr. Parisian had ever heard of Prolift +M was when she was asked to look at it for litigation. PM Dep. 61:25-62:4. She has no idea how many Prolift +M devices have been implanted in the United States or the world. *Id.* 62:5-7. She has never seen a Prolift +M implanted in the body in a live setting, has never watched a video of the procedure, has never held the device in her hand, and has never been in the same room with a Prolift +M device. *Id.*

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[5] *See, e.g.*, PM Rep. Opinions 1, 2, 9, 10; TVT-S Rep. Opinions 1-7.

[6] Also with respect to her "manufacturing" opinions on laser cut mesh, she testified that she has not seen any clinical data that indicates that laser cut mesh is dangerous to patients. PM Dep. 149:6-50:7.

62:9-22. She could not discern at her deposition between the instructions for use (IFU) for three different Prolift products, and was only able to offer a "guess" because she was "not sure which one" was which. *See id.* 64:24-65:25.

Dr. Parisian is not qualified to offer opinions on scientific aspects of urogynecology and material science. This very issue—Dr. Parisian's lack of qualifications on scientific issues—was recently discussed in *In re Mirena IUD Prods. Liab. Litig.*, -- F. Supp.3d --, 2016 WL 890251, *51-53 (S.D. N.Y. Mar. 8, 2016). There, Dr. Parisian sought to offer opinions on the plaintiffs' theory of "secondary perforation" (i.e., that Mirena could migrate out of the uterus unrelated to insertion) and other scientific issues. *Mirena*, 2016 WL 890251, *52. The district court determined that Dr. Parisian lacked the necessary qualifications to offer this testimony: "Dr. Parisian is a medical doctor, but she has no expertise or special skills related to the uterus or IUDs, nor is she a gynecologist." *Id.* *52; *see also id.* *53 (also finding Dr. Parisian not qualified to opine on a potential alternative, safer design for Mirena; "Dr. Parisian is not an engineer, nor has she ever designed IUDs, nor does she have any particular expertise in IUDs."). Similarly, the *Mirena* court found Dr. Parisian unqualified to "testify generally about medical standards." *Id.* *56.

Other federal courts have similarly refused to permit Dr. Parisian to opine on scientific issues. In *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp.2d 1323, 1337 (S.D. Fla. 2010), the court explained that "Dr. Parisian is neither a causation expert nor an epidemiologist," and "[w]hile Dr. Parisian's Report contains many opinions on the findings of scientific studies related to Trasylol and the association of Trasylol with various health risks, the Report alone did not allow me to conclude with certainty whether Dr. Parisian's experience at the FDA qualifies her to make such opinions . . . ."

Other courts are in accord. *See Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *4-5 (E.D. La. Mar. 30, 2000) (in case involving hernia mesh, excluding Dr. Parisian in case involving ventral adhesion repair where Dr. Parisian clearly stated at her deposition that she has never worked with that or any other kind of mesh, is not a surgeon, and has never performed any medical research); *see also, e.g., Bartoli v. Novartis Pharms. Corp.*, 2014 WL 1515970, *6 (M.D. Penn. Apr. 17, 2014) (excluding Dr. Parisian as not qualified on ethical standards or causation: "Dr. Parisian is not an expert in ONJ, and does not currently treat patients."); *Rowland v. Novartis Pharms. Corp.*, 9 F. Supp.2d 553, 563 (W.D. Pa. 2014) (ruling that Dr. Parisian may not offer an opinion about causation testimony of any kind, as she is not qualified); *Mathews v. Novartis Pharms. Corp.*, 2013 WL 5780415, *24-25 (S.D. Ohio Oct. 25, 2013) (excluding Dr. Parisian on "regulatory causation" and noting that many courts have "[found] her unqualified to offer an opinion related to the cause or diagnosis of ONJ"); *Stambolian v. Novartis Pharms. Corp.*, 2013 WL 6345566, *9 (C.D. Cal. Dec. 6, 2013) ("Dr. Parisian is not permitted to testify to things outside of her expertise. This includes testimony that may be couched as regulatory causation but in actuality speaks to medical causation. Dr. Parisian is not qualified to testify to the causal connection" between the products and alleged injury); *Taylor v. Novartis Pharms. Corp.*, 2013 WL 5118945, *7 (S.D. Fla. Apr. 22, 2013) (Dr. Parisian's "background does not reflect that she is generally aware of industry standards surrounding pharmaceutical companies."); *Hogan v. Novartis Pharms. Corp.*, 2011 WL 1533467, *40 (E.D. N.Y. Apr. 24, 2011) (finding Dr. Parisian unqualified to opine on pharmaceutical companies' standards); *In Re Heparin Prod. Liab. Litig.*, 2011 WL 1059660, *8 (N.D. Ohio Mar. 21, 2011) ("I also concur with [other] courts' findings that Dr. Parisian is not qualified to offer testimony as to medical or physiological causation issues."); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 468

(E.D. N.Y. 2011) ("Dr. Parisian is not qualified to opine on the ethical standards in the pharmaceutical industry, nor is she qualified to testify as to any obligations Novartis may have had to the medical community in addition to FDA requirements."); *Lopez v. I-Flow Inc.*, 2011 WL 1897548, *11 (D. Ariz. Jan. 26, 2011) (excluding Dr. Parisian where she was not qualified to opine on warnings to health care providers or patients); *In re Prempro Prods. Liab. Litig.*, 2010 WL 5663003, *2-3 (E.D. Ark. Sept. 16, 2010) (excluding experts including Dr. Parisian whose "expertise does not qualify them to provide a jury with a reasonable standard of care or a custom and practice"); *Reece v. Astrazeneca Pharms., L.P.*, 500 F. Supp.2d 736, 745-56 (S.D. Ohio 2007) ("although she is a medical doctor, plaintiff has not demonstrated that there is anything in Dr. Parisian's background or training that qualifies her to testify as an expert on chronic pain patients, rhabdomyolysis, or renal failure").

Dr. Parisian is not qualified to offer expert testimony on scientific issues, including causation, product development, risks, design, testing, manufacturing, studies, or the standard of care for treating physicians, and she accordingly does not support her vast arrange of scientific opinions with any sufficient methodology. Any opinions involving such testimony should be excluded.

B. <u>All Products</u>: Dr. Parisian should be precluded from offering testimony about Ethicon's intent, motive, state of mind or bad faith because she is not qualified to offer those opinions; she does not have a reliable basis for her opinions; and these opinions are irrelevant.

Dr. Parisian also claims that she will not offer opinions "regarding Ethicon's intent or state of mind." PM Rep. ¶23; TVT-S Rep. ¶23. Yet again, the opinions and statements in her report belie that statement. As the opinions below reveal, she intends to present the jury with her beliefs on Ethicon's "corporate willingness," lack of "commitment to conduct[ing] robust … surveillance," management decision to discontinue sales rather than obtain information about the

product for doctors and patients, and failure to adhere to the "company's code of conduct to conduct business with integrity and do the right thing . . . ."[7]

Dr. Parisian clearly intends to share with the jury her beliefs about Ethicon's knowledge, its state of mind, and whether it acted reasonably. The Court has found this to be impermissible expert opinion. *See, e.g., Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *3 (S.D. W. Va. Apr. 28, 2015) ("As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably."); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013), *on reconsideration in part* (June 14, 2013) ("Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.") (internal citations omitted).

Other federal courts have similarly excluded this testimony specific to Dr. Parisian. *See, e.g., In re Mirena*, 2016 WL 890251, *54 (excluding Dr. Parisian from testifying as to the state of mind, knowledge or motives of the defendant as she was unqualified to "divin[e] the concerns or motives or others"); *In re Trasylol*, 709 F. Supp.2d at 1338 (excluding Dr. Parisian from offering corporate intent or motive testimony, i.e., "personal 'bad company' opinions not based on any FDA regulation or other applicable standard" because the testimony lacked expert analysis and had only "marginal relevance"); *Lopez*, 2011 WL 1897548 at *11 ("Dr. Parisian's report lacks reliability and helpfulness to the jury in other ways as well. In many instances, Dr. Parisian opines as to the knowledge, state of mind, intent or motivates of I-Flow, other Defendants or the FDA itself. . . . Dr. Parisian has no knowledge of [these issues] and such

[7] *See, e.g.*, PM Rep. Opinions 1, 2, 13; TVT-S Rep. Opinions 1, 2, 4, 5.

testimony is improper under Rule 702 as well as Rules of Evidence 104 and 103. Myriad other courts have observed and excluded this type of testimony in Dr. Parisian's reports in the past.") (collecting cases specific to Dr. Parisian).

In addition, Dr. Parisian's Prolift +M Report, Opinion #1, contains several paragraphs on a regulatory action against Johnson & Johnson involving LifeScan products. *See* PM Rep. ¶¶95-99. This is altogether irrelevant and inadmissible. Not only does it involve a different product (and one that does not contain mesh), this is an obvious attempt to cast the parent company as a "bad actor." This violates the *Daubert*/Rule 702 principles articulated above. It is also inadmissible under Rules 401 and 402 (relevance) and Rule 403 (substantially outweighed by danger of unfair prejudice), as well as Rule 404 (impermissible character evidence).

C. <u>All Products</u>: Dr. Parisian's regulatory opinions are inadmissible because they are irrelevant; amount to legal conclusions; and constitute impermissible "narrative" testimony lacking adequate analysis.

(1) Any opinions premised on misleading or withholding information from the FDA are irrelevant and inadmissible.

Many of Dr. Parisian's opinions are premised on her personal belief that Ethicon withheld information from the FDA or engaged in actions that misled the FDA.[8] These opinions are inadmissible. This information is irrelevant; as this Court has ruled, "whether Ethicon violated particular sections of the FDCA or failed to furnish information to the FDA are not facts in issue in this case under Federal Rule of Evidence 702." *Lewis v. Ethicon, Inc.*, 2014 WL

[8] *See, e.g.*, PM Rep. Opinions 1, 3-11; TVT-S Opinions 1-8.

186872, at *19 (S.D. W. Va. Jan. 15, 2014).[9] Any opinion that Ethicon submitted false and misleading information to the FDA is preempted; is an irrelevant legal opinion; and is irrelevant to the jury's determination of liability. It should therefore also be excluded under Rules 401 and 403.

(2) Dr. Parisian's report contains impermissible legal conclusions.

Dr. Parisian's report is likewise inadmissible as she seeks to offer legal conclusions. Each of her opinions either states a legal conclusion itself—or is supported (by her) with a legal conclusion. In addition to the numerous statements in Dr. Parisian's report which impermissibly seek to apply the Food Drug & Cosmetic Act, her legal-conclusion-heavy approach is evident in the many statements concerning alleged duties owed by Ethicon, non-adherence to non-delegable responsibilities, or purported failure to evaluate foreseeable risks, adequately warn physicians, or comply with current safety and ethical standards.[10]

An expert may not offer "ultimate question" testimony that Ethicon's actions were inadequate: testimony containing legal conclusions impermissibly conveys a witness's unexpressed, and perhaps erroneous, legal standards to the jury. *See, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Heparin*, 2011 WL 1959660 at *8. Thus, Dr. Parisian "may not offer opinion testimony as to the reasonableness of the Defendants' conduct." *Id*. (excluding Dr. Parisian on this basis). *See also,*

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[9] Moreover, the FDA is the only entity in a position to determine whether it has been misled. For this reason, the court in *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp.2d 1312, 1329-30 (S.D. Fla. 2010), held that evidence of what information was or was not given to the FDA is only relevant to a fraud on the FDA claim, which is preempted by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350–51 (2001).

[10] *See, e.g.*, PM Rep. Conclusion, ¶¶273-275; TVT-S Rep. Conclusion, ¶¶318-319.

e.g., *Pritchett v. I-Flow Corp.*, 2012 WL 1059948, *6 (D. Col. Mar. 28, 2012) (Dr. Parisian's "lengthy written report occasionally lapses into unadulterated legal conclusions which are not only beyond her purview, but which usurp the important functions of the judge and jury;" citing examples from her report and ruling that "[t]his use of legal terminology and concepts to render legal conclusions is outside of Dr. Parisian's area of expertise and improperly invades the provinces of both the jury and the court.").

(3) Dr. Parisian merely provides an unsupported "narrative" or "regurgitation of facts" to explain her opinions.

Dr. Parisian's testimony regarding regulatory history is also subject to exclusion as an impermissible narrative or, as some courts have deemed her testimony, a "regurgitation of facts." *See, e.g.*, *In re Mirena*, 2016 WL 890251 at *53. As the district court explained in *In re Fosamax Prods. Liab. Litig*., 645 F. Supp.2d 164 (S.D. N.Y. 2009) in addressing Dr. Parisian, "[a]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on record evidence." *In re Fosamax*, 645 F. Supp.2d at 192. The court excluded Dr. Parisian's testimony on this basis, stating as follows:

> In detailing the factual basis for her opinions, Dr. Parisian's report presents a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory filings, and the deposition testimony of Merck employees. The Court agrees with Merck that, to the extent such evidence is admissible, it should be presented to the jury directly. Dr. Parisian's commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge. She will not be permitted to merely read, selectively quote from, or "regurgitate" the evidence.

Id. The court also cited *In re Prempro Prods. Liab. Litig*., 554 F.Supp.2d 871, (E.D. Ark. 2008), which overturned a punitive damages award based on Dr. Parisian's testimony in part because she "did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony" and "did not provide analysis, opinion, or expertise." *Id*. at 880, 886.

Other courts have ruled similarly, finding Dr. Parisian's *modus operandi* to provide a "narrative of selected regulatory events and a summary of [internal] documents," where she "merely recites the [FDA's understanding]" without sufficient references to FDA regulations in recitation of the facts. *See, e.g., In re Trasylol*, 709 F. Supp.2d at 1338 (finding that Dr. Parisian "does not tie [the regulatory facts] to the opinions that they are intended to support."); *Kaufman v. Pfizer Pharms., Inc.*, 2011 WL 7659333, *10 (S.D. Fla. Aug. 4, 2011) ("[w]hile Dr. Parisian devotes several pages of her report to restating and analyzing FDA regulations, she does not apply any of these regulations . . . to her report."); *see also Lopez*, 2011 WL 1897548 at *10 ("Dr. Parisian's report is a labyrinth that the Court cannot navigate. . . . Dr. Parisian's report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation. . . . This deficiency has also been noted by other courts in excluding such testimony from Dr. Parisian."); *Miller v. Stryker Instr.*, 2012 WL 1718825, *11 (D. Ariz. Mar. 29, 2012) (excluding Dr. Parisian because "much of [her] report regurgitates facts that should be submitted directly to the jury" and where she provided "no analysis or explanation" of her conclusory assertions); *Pritchett*, 2012 WL 1059948 at *7 (D. Col. Mar. 28, 2012) (excluding portions of Dr. Parisian's testimony "regurgitating factual information that is better presented through introduction of documents or non-expert testimony").

Dr. Parisian's report, here, follows the same pattern. Each report contains page after page of references to internal documents—untethered to any explanation of how this vast cache of documents actually supports her opinions. Dr. Parisian's reports otherwise provide a mere bullet-point/paragraph listing of FDA regulations, amounting to handfuls of unexplained and

unapplied references to unidentified aspects of federal law. This testimony—as other courts have found—is not reliable nor is it helpful to a jury as Rule 702 requires.

D. <u>All Products</u>: Dr. Parisian should not be permitted to opine on foreign regulatory matters because she is not qualified; she does not employ a reliable methodology; and this testimony would not be helpful to the jury.

Dr. Parisian expects to testify on issues including "foreign data," and she refers to foreign regulations in her report. *See e.g.*, PM Rep. ¶¶18, 68, 110, 112, 137-138, 187-188, 203, 208-209. Dr. Parisian, however, is not qualified to offer expert testimony on foreign regulatory matters: she attests only to a "working familiarity" with "International standards and requirements"—hardly a basis to deem Dr. Parisian qualified as an expert to present this material to a jury. *E.g.*, PM Rep. ¶18. As the district court found in *In re Mirena*, "Dr. Parisian will not be allowed to opine on foreign regulatory issues. Dr. Parisian is admittedly not an expert in the laws of foreign jurisdictions, and therefore is not qualified to testify on those subjects." *In re Mirena*, 2016 WL890251 at *53. In addition, as here, "[t]here is no reason to believe that the regulatory framework of [other countries] is similar to the FDA's system." *Id*. (also finding that Dr. Parisian's report and proposed testimony in this area "is a recitation and reports and regulatory actions, with little or no analysis, which is not proper expert testimony" and ruling that "she may neither summarize foreign regulatory history nor imply that an action required abroad was necessarily required in the U.S."). Any opinions by Dr. Parisian on foreign regulatory issues should thus be excluded.

E. <u>Prolift +M</u>: Dr. Parisian is not qualified to opine on warnings and she does not apply a reliable methodology regarding the alleged inadequacy of the Prolift +M warnings.

(1) Dr. Parisian is not qualified in this matter to opine on warnings.

Whereas some courts have found Dr. Parisian to be sufficiently qualified to opine on product warnings, *see, e.g., In re Mirena*, 2016 WL 890251 at *55, Dr. Parisian's testimony

reveals that in this case, she is not adequately qualified to offer opinion testimony. *See, e.g.*, *Rowland*, 9 F. Supp. 2d at 562 (excluding Dr. Parisian as unqualified to testify what prescribing oncology physicians would have done with different warnings because it would require an impermissible degree of speculation from Dr. Parisian, who is not an oncologist); *Reece*, 500 F. Supp. 2d at 745-46 (S.D. Ohio 2007) (excluding Dr. Parisian from offering testimony on, e.g., whether defendants provided physicians with adequate warnings: "plaintiff has not demonstrated that there is anything in Dr. Parisian's background or training that qualifies her to testify as an expert on chronic pain patients, rhabdomyolysis, or renal failure;" also finding that she did not use a scientifically valid methodology to reach her conclusions where she had not performed any testing or research to support her theory.

In addition to the details of Dr. Parisian's experience set forth above (e.g., lack of any experience with or testing of mesh), the following, additional facts point to Dr. Parisian's lack of qualifications as directly bearing on warnings.

During Dr. Parisian's four-year position at the FDA, she was never involved with (1) Prolift +M or its FDA review, (2) any mesh products for pelvic organ prolapse, or (3) any pelvic floor repair device. PM Dep. 52:4-53:7. She has never drafted an IFU or patient brochure that she believes is adequate. *Id*. 66:23-25. She has not provided edits or changes to the existing Prolift +M patient brochure or IFU that would, if adopted, make it adequate, except a general criticism that frequency information should have been included. *Id*. 67:2-6; 68:11-15, 127:11-128:14.[11]

[11] In fact, Dr. Parisian has never found *any* mesh IFU which she believes to be adequate. PM Dep. 135:9-20.

In addition, Dr. Parisian could not recall, during her deposition, whether she had even seen the patient brochure for the Prolift +M—even though she seeks to tell the jury that it was inadequate. PM Dep. Tr. 88:25-89:8; 116:4-10; 161:13-162:4.[12] Dr. Parisian has never spoken with a physician who has implanted a Prolift +M device and she has not read the deposition of any physician who has implanted the device. *Id*. at 69:2-7. She has not conducted any survey of pelvic floor surgeons to determine whether they read the IFU—nor has she surveyed what risks they understood as a result of reading the Prolift +M IFU, or what they understand from their medical education, surgical training, medical literature, experience implanting other devices, training on the Prolift +M, or Ethicon-sponsored training *Id*. 83:5-84:12; 85:24-86:3; 86:4-23; 87:6-19. When asked if there is medical literature that implanting physicians should read, Dr. Parisian responded:

> It depends. I don't know. It depends on the surgeon, what – how they learn stuff. What they're – what they're doing.

Id. at 85:3-20. And when asked what the words in the IFU would mean to a pelvic floor surgeon, she could not answer:

> Q. Would a surgeon reading the Prolift+M IFU know from reading this IFU that Prolift+M had not been studied in randomized clinical trials? Yes or no? If you can answer that yes or no.
>
> ***
>
> A. Well, I can't speak for what any one surgeon would know, but I can speak as a regulatory expert.

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[12] It stands against the scientific method for Dr. Parisian to have formed her opinions prior to reviewing the materials on which she now claims to rely. *See Claar v. Burlington N. R.R.*, 29 F.3d 499, 502-03 (9th Cir.1994) ("Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method."). These opinions are litigation driven, unreliable, and should be excluded.

Id. at 129:22-130:8 (objections omitted).

(2) Dr. Parisian does not know the risks of non-mesh or mesh procedures and she has not employed a reliable methodology to arrive at her opinions on adequacy of the warnings.

Dr. Parisian also admitted at her deposition that she does not know the risks of non-mesh pelvic organ prolapse surgeries. PM Dep. 98:23-99:6. When asked if chronic dyspareunia is a risk of non-mesh surgery, she responded: "And I would say I don't know." *Id*. 100:7-21. She did not know if de novo chronic dyspareunia is a risk of a non-mesh surgery to treat pelvic organ prolapse. *Id*. 101:3-103:6. She did not know whether vaginal scarring is a risk of a non-mesh surgery to treat pelvic organ prolapse, *id*. 103:7-14, or if urinary problems were risks of a non-mesh surgery. *Id*. 103:21-104.

Dr. Parisian testified that she does not know if there are patients who have had the Prolift +M device who experienced no complications, had good experiences, or found the device to be safe and effective; nor does she know if a significant number of doctors believe the product is safe and effective. PM Dep. 63:2-13. And in response to questions regarding whether the medical community knew of various risks of mesh devices in 2008, Dr. Parisian could only respond with "I don't know" or "I can't answer that:"

Q. Dr. Parisian, I'm very specific, just asking you this question: Was chronic dyspareunia with mesh devices known to the medical community in 2008?

A. I don't know. I can't talk for every -- I mean, again, it would be the physician that's caring for the patient.

Q. Was the risk of chronic pain with mesh devices known to the medical community in 2008?

A. I can't speak for what the medical community knows.

Q. Was the risk of vaginal scarring with mesh devices known to the medical community in 2008?

A. You know, I can't speak for the whole medical community. I don't think so.

Q. Was the risk of urinary problems with mesh devices known to the medical community in 2008?

A. Well, you're talking about general. You're not talking about Prolift+M?

Q. Correct.

A. You're just talking general. I don't know.

Q. Was the risk of organ and nerve damage with mesh devices known to the medical community in 2008?

A. I don't know.

Q. Was the risk of bleeding and wound complications with mesh devices known to the medical community in 2008?

A. Again, I can't answer that. I mean, these are complications of surgery, but whether an individual surgeon who was putting this in knew that, I can't answer that.

Q. Was the risk of inflammation with mesh devices known to the medical community in 2008?

A. I can't answer it.

Q. …Was the risk of fistula formation with mesh devices known to the medical community in 2008?

A. I don't -- I don't know if it was or not, and that was part of the issue that the FDA came out with that public health notification is that they were concerned that people weren't aware of the risks.

Q. Was the risk of neuromuscular problems with mesh devices known to the medical community in 2008?

A. I don't know. Same answer.

Q. Was the risk that a surgery involving a mesh device might necessitate one or more surgeries to treat an adverse event known to the medical community in 2008?

A. I don't think so, and I can't answer for the medical community. That was why the FDA was asking for that information.

Q. Was the risk of erosion, exposure, extrusion with mesh devices known to the medical community in 2008?

A. Again, I can't answer that.

Q. Was the risk of contraction or shrinkage of the mesh known to the medical community in 2008?

A. Same answer.

Id. 112:2-115:13 (objections omitted).

To put it simply, there is a *lot* that Dr. Parisian just doesn't know. Her lack of understanding renders her unqualified to opine about warnings. And her lack of any stated methodology or research to support her theory renders her opinions on warnings unreliable. She offers opinions based on personal belief and mere speculation.

This lack of qualifications and reliable methodology is indelibly tied to Dr. Parisian's ability to offer an *expert* opinion to the jury about whether the product IFU and patient brochures were adequate to warn surgeons of the known risks of the product. As district courts recognize, to opine about the sufficiency of a warning, the expert must "have a sufficient basis for understanding what information is needed by a doctor in making his or her prescribing decision. Without knowing the baseline of what information is needed, it is not possible to opine meaningfully on the information's adequacy for that purpose." *Calisi v. Abbott Labs*, 2013 U.S. Dist. LEXIS 139257, *26 (D. Mass. Sept. 27, 2013) (excluding regulatory expert's opinion about sufficiency of warnings for a physician); *see also In re Welding Fume Prods.*, 2005 WL 1868046, at *7 (N.D. Ohio Aug. 8, 2005) (excluding expert's opinion regarding adequacy of the warning because the incorrect standard applied by the expert "does not necessarily translate to a legal warning requirement, nor does it necessarily imply liability"); *Am. Med. Sys. v. Laser Peripherals, LLC*, 712 F. Supp. 2d 885, 900-901 (D. Minn. 2010) (excluding expert's testimony where she provided correct legal standard in expert report but did not apply it correctly).

Here, Dr. Parisian provides no basis for her opinion of what Ethicon "should have done" and is likely the result of Dr. Parisian's lack of expertise in warnings and labels for medical devices. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611 (granting motion to exclude plaintiff's warnings expert who had never developed a warning or a label, who had no familiarity

with federal regulations regarding IFUs and who had no familiarity with whether FDA or other manufacturers' IFUs include supporting data; the expert was "unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process. To the extent that Dr. Shull seeks to opine that surgeons did not receive adequate warnings from Bard, he is similarly unqualified to do so.").

F. TVT-Secur: Dr. Parisian's testimony about the TVT-Secur's warnings should be excluded because she is not qualified and fails to use a reliable methodology.

Dr. Parisian also seeks to offer testimony that the TVT-Secur warnings were inadequate: her report claims that the labeling "failed to warn physicians of the difficulties of the insertion for SUI, the difficulties experienced with the insertion tools and the significant learning curve seen in physicians already familiar with this type of surgery." TVT-S Rep. ¶319. She further contends that the labeling had inadequate directions for use and "inadequate warnings and lack of adequate information about potentially serious, permanent and life-altering risks for the product when implanted for SUI." *Id.*

The same shortcomings in Dr. Parisian's warnings opinions as identified above with Prolift +M—i.e., her lack of sufficient qualifications or a reliable methodology—are found in Dr. Parisian's TVT-S testimony. Of note, Dr. Parisian's testimony on this product is contained both in the March 8, 2016, deposition testimony in MDL 2327, as well as testimony on February 12, 2015 (for the same product) in *Garcia v. Walss et al.*, 103rd Judicial District, Cameron County, Texas (No. 2013-DCL-3511-D). *See* Exh. F: Parisian 3/8/16 TVT-S Dep. Tr. ("TVT-S Dep. Tr.") 7:18-8:6 (parties' agreement that the deposition in *Garcia* may be used as in the MDL); Exh. G: Parisian 2/12/15 (Garcia) TVT-S Dep. Tr. ("Garcia Dep. Tr.").

(1) Dr. Parisian is not qualified to opine on the TVT-S warnings.

Dr. Parisian admits, without reservation, that she developed her opinions specifically for purposes of litigation, not for any type of research or study. TVT-S Dep. Tr. 62:23-63:1. Like the testimony described above for the Prolift +M, Dr. Parisian has insurmountable shortcomings in relation to the TVT-S warnings.

As she explained in *Garcia*, she has never practiced medicine in the fields of surgery, gynecology, urology, or urogynecology. Garcia Dep. Tr. 94:12-95:8. Dr. Parisian has no experience treating women for SUI with surgical mesh and, in fact, has no surgical expertise. *Id*. 94:12-13; 99:2-6. She has never seen how a TVT-Secur is implanted, has never implanted one herself, and admits that she lacks the expertise to do so. *Id*. 99:18-23; 114:2-10.

Dr. Parisian has never designed pelvic mesh or any other product from the treatment of SUI. Garcia Dep. Tr. 101:20-24. She has never designed a clinical trial for surgical mesh or for any SUI product. *Id*. 101:9-14. She has never conducted any clinical research regarding surgical mesh or SUI. *Id*. 101:15-19. Dr. Parisian has never conducted any biomechanical testing for pelvic mesh in general and has never tested the TVT-Secur device. *Id*. 102:1-4. She has never conducted any biocompatibility studies for the mesh and has not conducted any clinical trial or clinical research regarding polypropylene. *Id*. 116:21-23. She has never performed a Device Design Safety Analysis or a Failure Mode Evaluation Analysis. *Id*. 103:15-104:4. Dr. Parisian admits she is not an expert in the design process for pelvic mesh. *Id*. 104:18-105:7.

More recently, in her MDL deposition, Dr. Parisian testified that she never had any involvement with TVT-S (or its predicates) while at FDA. TVT-S Dep. Tr. 66:14-24. She has still never done any type of testing of the mesh for TVT-S. *Id*. 67:5-20. Dr. Parisian reaffirmed she has never seen a TVT-S implanted in the body; has never watched a video of the procedure; and has never held or even been in the same room as the TVT-S. *Id*. at 68:23-69:13. She agreed

that she does not have the requisite education, training, and experience to implant a TVT-S or to counsel a patient. *Id.* at 69:18-70:2. When asked if she would counsel patients, she acknowledged "I don't think that I would be the right person to counsel somebody about [treatment options for SUI]." *Id.* at 67:21-68:22. She confirmed that since her *Garcia* testimony, she has not conducted any survey or study of pelvic floor surgeons to determine what they understood regarding the product from reading the IFU, from their medical school education, from their surgical training, or from reading medical literature. *Id.* 102:24-105:8.

Like her Prolift +M testimony, Dr. Parisian does not know whether there are patients who have had TVT-Secur without complications: she testified "I don't know what the patient experience is." TVT-S Dep. Tr. 70:3-9. She does not know if there are women whose TVT-S has been a safe and effective device, and she does not know if there are pelvic floor surgeons who believe the TVT-S was safe and effective. *Id.* 70:10-71:1. Dr. Parisian seeks to opine on the warnings, but she has never written a draft IFU or patient brochure. *Id.* 71:2-5. She has not identified what words needed to be added or removed from the TVT-S IFU to make it adequate. *Id.* 71:6-13.

Similar to her testimony in *Garcia*, Dr. Parisian confirmed in her MDL testimony that she has never spoken with a doctor who has implanted a TVT-S; she has never spoken to a pelvic floor surgeon about the TVT-S; and she has read only one deposition of an implanting physician (in *Garcia*). TVT-S Dep. Tr. 71:14-72:1; 84:4-18. She did not review any professional education materials regarding TVT-S. *Id.* 72:16-20, 75:17-78:8. She has not conducted any survey or study of pelvic floor surgeons about the risks they would understand from reading the patient brochure. *Id.* 84:16-85:3. And like her testimony on the Prolift +M, *supra*, Dr. Parisian does not know the risks that were associated with the TVT-S. *Id.* 93:10-101:5.

Despite her dearth of experience, despite having performed no tests, clinical trials, or research on the design of surgical mesh generally or TVT-S specifically, despite never having spoken to any physician about the IFU or patient brochure, and despite not knowing the risks at the pertinent timeframe, Dr. Parisian nevertheless seeks to opine on the warnings provided to pelvic surgeons for the TVT-S. Nothing about Dr. Parisian's knowledge, skill, experience, training, or education remotely qualifies her to offer these opinions. She should be precluded from offering any opinion on these subjects based on her lack of sufficient qualifications.

(2) Dr. Parisian does not apply a reliable methodology for her TVT-S warnings opinions.

Her opinions also fail for lack of reliable methodology. Dr. Parisian's criticism of the TVT-Secur IFU is based solely upon her subjective belief that the document is insufficient. She admits that the FDA never found the material in the IFU to be deficient. Garcia Dep. Tr. 232:17-233:23. Additionally, the FDA never proposed any label changes for the TVT-Secur IFU. *Id.* 232:8-233:23. Dr. Parisian's criticisms of TVT-Secur IFU are not based on any methodology: Dr. Parisian did not conduct a readability study of the TVT-Secur IFU, *id.* 124:5-124:13, and did not conduct a survey of surgeons to determine what information the surgeons gleaned from the IFU. *Id.* 121:8-121:22. In fact, she has never spoken with a medical doctor about her criticisms of the IFU. *Id.* 33:16-33:18.

As the cases cited in Section E discuss, Dr. Parisian seeks to offer opinions on the TVT-S warnings that are far beyond her background or training. She is not qualified under these circumstances and does not apply a reliable methodology. Accordingly, her TVT-S warnings opinions should be excluded.

G. Dr. Parisian should not be permitted to testify as to any product other than Prolift +M or TVT-Secur (*see* Exhibit A).

Finally, Dr. Parisian has been designated as an expert in seven cases which involve either Prolift +M or TVT-Secur, which are the two products for which she prepared an expert report. *See* Exh. A. She was also designated as an expert in an additional 37 cases involving other mesh products; however, Dr. Parisian did not provide an expert report for those cases. The parties have entered into a Stipulation, filed in each of those respective 37 cases, whereby those Plaintiffs have withdrawn their expert designation for Dr. Parisian.

CONCLUSION

For these reasons, Ethicon's motion to exclude Suzanne Parisian, M.D., should be granted and Dr. Parisian's testimony should be excluded in its entirety. Ethicon prays for all other relief to which it is entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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